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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,405	01/26/2004	Naishu Wang	2128.1-5	2201

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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,405	WANG, NAISHU	
	Examiner	Art Unit	
	Natalia Levkovich	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a first and a second positions of the distribution valve in terms of functional language. The structural inter-relations between the elements of the apparatus for each claimed position are unclear.

Claim 2 recites: "The apparatus of claim 1, wherein said pan, vessel and station define an enclosed chamber for holding said sampling; said device further comprises a receptacle above said pan for holding a reagent, said receptacle having an opening; and said valve comprises means for exposing said chamber to said opening when said valve is placed in said first position". The structural inter-relations between the receptacle with the opening, the valve and the vessel (recited in claim 1) are not sufficiently outlined in the claims. The receptacle, the opening in the receptacle and the 'means for exposing said chamber to said opening' are not disclosed in the Specification. It is also unclear whether the 'reagent' held by 'receptacle' is an

Art Unit: 1743

immunoassay reagent or a specimen. The receptacle is also recited in the similar manner in claim 11.

For the examination purposes, the Examiner assumes that a specimen is meant by the term 'reagent' and that the term 'receptacle' coincides with the term 'cavity' recited in claim 8.

Claim 5 recites "two isovolumetric portions ... having inlets controlled by said valve". Since the inlets are not supported by the Specification, their location, as well as their structural inter-relation to the valve, remain unclear.

Claim 8 recites means for rotating the cylindrical body of the valve. The above means are not distinctly identified in the Specification, which renders claim 8 indefinite.

Claim 10 recites means for exposing the pan and the station to a desiccant. The above means are not distinctly identified in the Specification, which renders claim 10 indefinite.

Claim 15 recites means for maintaining said sampling into said chamber under isobaric condition. The above means are not distinctly identified in the Specification, which renders claim 15 indefinite.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

Art Unit: 1743

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 1 is rejected under 35 U.S.C. 102(e) as anticipated by

Hudak (US 20030022392).

Hudak discloses an integrated sample collection and handling device comprising, as shown in Figure 1, a chamber 100 ['collecting vessel' – Ex.] capable of collecting a specimen; a reservoir 300 ['base pan' – Ex.] capable of receiving a portion of the specimen from the chamber; a valve 200 interposed between the chamber and the reservoir and capable of transferring "at least a portion of the specimen from the chamber to the reservoir"; and a test device 500. "The chamber 100 can have a side wall 104, a bottom wall 106" and a chamber orifice 108 in the bottom portion of the chamber—(See Abstract; [0031], [0035], [0036]).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1743

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hudak supra in view of Cui et al. (US 20030206829).

With respect to claims 2 and 3, Hudak does not teach a receptacle having an opening capable of accommodating a desiccant. Cui discloses fluid handling apparatus and methods for collecting and testing devices and methods for collecting and testing a fluid specimen allowing to avoid "unduly exposing the tester to the specimen and eliminate the possibility of contaminating the remaining portion of the collected fluid" (Abstract). Shown in Figure 1 are different embodiments of valve cylinders 26 "varying in well ['receptacle' – Ex.] arrangements and well dimensions. As indicated in the figure, a cylinder can have one or more rows of wells, each row of a similar dimension and forming a single line along the longitudinal axis of the cylinder. Separate rows may be situated at opposite positions on the cylinder surface (i.e., 180.degree. from each other) or may be situated closer together. In addition, a cylinder may have more than two rows of wells". "Clearly, one of ordinary skill can readily envision a variety of cylinder designs with combinations of wells and rows" (See [0029] [0030]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed a valve having receptacles arranged in such a manner that the reservoir ['chamber'] would be exposed to a drying agent / desiccant (when the valve is in the 'first position', that is the reservoir is not filled with the fluid, in the modified apparatus of Hudak, in order to provide clean and dry environment for the next

portion of a specimen and in order not to pose a potential hazard to the technician.

Referring to claims 4, 5, 7 and 15, Hudak does not specify the apparatus having two test stations and two 'isovolumetric' portions of the 'liquid-receiving' chamber, the portions being connected to the stations via passageways / channels. Cui discloses an embodiment (shown in Figure 4) of the apparatus comprising two test stations 28 connected to corresponding 'isovolumetric portions' / channels 40, 16.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed more than one test station communicating with fluid samples via connecting elements (such as portions of reservoirs, passageways or channels), the corresponding elements having equal volumes and being symmetrically arranged, in the modified apparatus of Hudak, in order to accommodate more test strips, to provide equal hydrodynamic conditions (including pressure) for the test strips, and to ensure reliable, precise and consistent measurements.


Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
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